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09/937,126	12/19/2001	Hans-Werner Heinrich	101195-63	6139

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

937,126

Applicant(s)

HEINRICH et al

Examiner

SPUNGER

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-17 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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The claims pending and under examination are 1-17.

The disclosure is objected to because of the following informalities: pages 4-5 and 7 recite various amino acid sequences. Identification of each by a SEQ ID NO from the sequence listing is required.

Appropriate correction is required.

The following misspellings have been noted.

--covalent-- at page 6, line 4

-- defense-- at page 6, line 20.

Claims 1-11 are objected to because of the following informalities: the first claim page fails to commence with --We claim--.

Claims 6-10 recite amino acid sequences without corresponding SEQ ID NOS. In claim 11, line 2, it is believed that "of" (first recitation) is intended to be --or--. Each of claims 6-10 fails to end with a period. Appropriate correction is required.

Claims 4-5, 11-14 and 16 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. Furthermore, claims 5, 11-14 and 16 improperly refer to other claims that are multiple dependent. See MPEP § 608.01(n).

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 1, 14 and 16 “if need be” is indefinite. Substitution of --optionally-- would be appropriate.

In claim 4 “are contained as” is unclear, since the “immunoabsorber” of claim 1 has not been defined as having any container as a structural element.

In claim 4 “the state of the dysregulation” lacks antecedent basis and is unclear because it is not clear as to what has been dysregulated. Is there an unrecited patient in claims 1 and 4?

In claim 5 it is not clear what “these antibodies” refers to -- to the “antibodies aimed against further sepsis mediators”?

Regarding claims 11 and 15, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 12 “the specific antibodies” lack antecedent basis. Claims 1 and 4-10 have recited “aimed against”. Recitation of --specific for-- in place of “aimed against” in these claims would overcome and would be art conventional.

In claim 12, “the membranes or particles” lack antecedent basis in claims 1 to 10.

In claim 15 “preferably” is indefinite.

In claim 16 “a patient-specific combination of body fluids” is unclear.

Claims 15-16 provides for the use of immunoabsorbers, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art, are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. Claims 1-5 and 11-17 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Matson et al. (6,287,516) in view of Davidner et al. (6,193,681), Surkovitch et al. (5,626,843) and Wang et al.

Matson et al teach the removal of the mediators of sepsis and of other inflammatory conditions via an extracorporeal device having a solid phase.

Mediators to be removed are listed at col. 2, lines 36-65 and at col. 11, lines 1-8. Therein, Matson et al. teach removal of "complement factors" generically, but they do not specifically teach C5a or C3a. Also Matson et al. teach the removal of endotoxin (col. 3, line 29) but not specifically to LPS.

Matson et al. also teach that combinations of specific antibodies may be used on the absorbent solid phase material. See col. 13, line 1- col. 14, line 44.

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Davidner et al. teach that C3a and C5a are considered to be among the complement factors that should be removed in the extracorporeal treatment of septicemia (col. 1, lines 45-60). They also teach that LPS should be removed (col. 7, lines 22-23). It thus would have been obvious to employ an apparatus taught by Matson et al. with surface bound antibodies for the removal of both C3a/C5a and LPS for treating sepsis.

Surkovitch et al. are relied up for teaching extracorporal immunoabsorbents prepared with multiple antibodies --e.g. against TNF and interferon. One thus would have recognized that there would be no difficulty in preparing immunoabsorbents having multiple polyclonal or monoclonal antibodies specific for multiple large antigens, such as interleukins and TNF or any other macromolecules.

Wand et al. are relied upon for teaching that it is known to prepare antibodies against low molecular weight peptides such as C5a. Thus one would not have expected any difficulty in providing anti C3a/C5a antibodies.

Claims 1-3 thus would have been obvious.

Regarding claim 4 (and 16) note Matson et al. teach a combination of adsorbent materials appropriate for a patient's

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condition -- e.g. col. 13, lines 28+; col. 14, lines 30+; col. 16, lines 49+.

Regarding claim 5, Matson et al. teach an antibody to TNF (col. 13, line 30).

With respect to claims 11-13, the Sepharose 4B bound antibody of Surkovitch et al. (col. 4, lines 1+) is consistent with these claims.

Claims 14-17 are conventional methods of preparing and using extracorporal immunoadsorbents.

Claims 6-10 contain limitations allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

June 19, 2003

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 *1644*